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Eliminating Standalone Technical Specs Helps Accelerate Study Start-Up

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The average time from protocol completion to study start-up is four months.{1} For data managers, the primary deliverable is the technical specification document that provides detailed instructions for configuring the electronic data capture (EDC) and other eClinical systems. The more complex the trial, the harder it is to describe the data collection requirements and provide accurate instructions for capturing and checking data quality in an EDC system.

Since the software engineers programming and testing the EDC often lack deep clinical expertise, granular instructions are needed. A 10-page document on data collection requirements can expand to a 100-page technical specifications document that is challenging and time-consuming for the study team to review.

Data management can improve quality and shave months from study start-up by eliminating these standalone specification documents for data collection instruments such as EDC casebooks. However, eliminating standalone specs may be welcome news for some, and sound impossible to others.

Kent Thoelke, executive vice president and chief scientific officer at PRA Health Sciences, recently warned against getting too comfortable with established practices in his keynote at the Society for Clinical Data Management conference. "As an industry, we are holding ourselves back using the excuse of serving in a regulated environment," Thoelke explained. "We are failing to embrace the opportunities and technologies that already exist today."

Moving forward, there are two ways EDC systems can eliminate the need for technical specs:

1. The TransCelerate Common Protocol Template and Digital Data Flow initiatives conceptualize a machine-readable protocol and EDCs that automatically generate a casebook based on that protocol.
2. EDC systems that can consolidate the authoring of specifications and developing the casebook into a single process within the EDC itself.

Automating EDC Casebook Creation, Leveraging a Digital Data Flow

The TransCelerate initiative called Digital Data Flow (DDF) aims to improve the speed and quality of study start-ups by automating the setup and configuration of eClinical systems using a standardized and machine-readable protocol defined by the Common Protocol Template.

The protocol would be built within a separate, standalone study definition tool that generates an

XML-based description of the study and data collection requirements. To create the protocol, a study designer would draw from a repository of stored definitions for standard design elements and configure those as needed for the individual study.

"The proposed system would capture digitized protocol elements and present them in standardized formats to enable automated configuration of downstream systems and efficient consumption of protocol information across the study ecosystem," according to TransCelerate.{2}

The DDF vision spans all systems used during study execution. Involving multiple systems improves downstream system interoperability and data quality, as well as increases the cumulative time savings.

The initial priority is to automate study configuration within the EDC.{2} The EDC would receive an XML output file from the study definition tool, and automatically create and configure a new casebook according to the specifications provided. Automating these processes would immediately reduce the time and effort required for study start-up.

The standards and technologies needed to support this vision would not only help speed study start-ups, but also reduce barriers to making mid-study changes. Any changes made within the central study builder could be easily propagated to downstream systems. Given that implementing changes typically takes 10 working days at a minimum, this type of operational efficiency would help make trials more agile.{3}

These TransCelerate initiatives are exciting and promising for the industry. However, the DDF effort is in early stages and a significant amount of work remains to be done. Therefore, companies should pursue interim steps that are possible today and aligned with the goals of adopting standards and automating system configurations during study start-up.

Fusing Specifications and Design Within the EDC

Combining the specification and design processes within the EDC can also eliminate standalone specification documents. With this approach, the study designer reads the protocol, defines the data collection requirements, and translates that vision into a functioning casebook within the EDC.

Modern technologies can increase the intelligence of an EDC system to understand study parameters and casebook design requirements. Now, data managers and study designers can work with a purpose-built interface for specifying data collection requirements. The result is a much simpler solution that no longer necessitates technical specifications to communicate requirements between people.

As an individual defines and configures the study using a visual design tool, the EDC generates metadata descriptions of each element. The schedule, forms, fields, rules, and data validation checks—are all stored as metadata that can drive the system. The EDC uses the metadata to automatically generate casebook pages, data validation checks, and rules. Writing the specifications and building the database become one.

A second advance in EDC technologies allows EDCs to be self-documenting. The configuration metadata are also used to generate a spreadsheet that documents every aspect and attribute of the casebook, including the study schedule, form definitions, rules, and more. A standalone specifications document remains important for compliance and sponsor sign-offs. Generating these automatically improves the speed, quality, and completeness of the spec while removing a long and onerous review cycle.

Creating specifications with a purpose-built tool is easier than working in generic applications such as spreadsheets because the constructs for data collection are pre-built. Users work from standard

design templates, drag-and-dropping pre-defined study elements like case report forms or individual data fields to compose the casebook. Configuration and simple edit checks are defined within the metadata.

More complicated rules and edit checks are scripted in a rules engine that provides pre-defined variables, functions, and actions to choose from. A technically savvy data manager or clinically savvy programmer can write all the rules and edit checks without traditional coding and without a spec, based on his or her understanding of the trial and data management requirements.

Conclusion

Speeding study start-up is a priority for all sponsors and contract research organizations (CROs). To help, data management teams can eliminate inefficient and manual aspects of their workstream, including the siloed technical specs created in spreadsheets and other documents.

The standardization and automation outlined in the TransCelerate initiatives would be transformational in terms of speed, quality, and simplification. If achieved, human errors and effort would be minimized while maximizing the opportunity for greater integration and data flows between clinical systems. Sponsors and CROs should be pushing their technology providers for metadata-driven systems and templates aligned with TransCelerate's vision.

A metadata-driven architecture enables dramatic productivity improvements, such as fusing EDC specifications and design into a single step. These are bold advances that will allow clinical researchers to spend more time focusing on science instead of their clinical systems.

References

1. Digital Data Flow. 2017. https://transceleratebiopharmainc.com/initiatives/digital-data-flow/
2. Executive Summary, Version 1.0 of TransCelerate's Digital Data Flow, Solution Framework, and Conceptual Design. 2019. http://transceleratebiopharmainc.com/wp-content/uploads/2019/11/DDF-SFCD-Executive-Summary_7Nov2019.pdf
3. Bondt JD. 2015. Innovative approach to building an adaptive trial design in Medidata Rave®. SGS Life Science Services. https://www.lexjansen.com/phuse/2015/ts/TS07.pdf

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